

Serial No.: 10/565,706  
Group Art Unit No.: 1611

### Amendments to the Specification:

Please replace the paragraph beginning on page 12, line 29 with the following:

- Solution preparation -
  - (a) Weigh all excipients except ~~Eudragit L100-55~~ EUDRAGIT® L100 55 (poly(methacrylic acid-co-ethyl acrylate) 1:1) and nicotine oil into a hydroalcohol/water solution (ethanol/water 60/40).
  - (b) Using high speed mixer, dissolve all solids in the hydroalcohol/water solution.
  - (c) Increase the mixing speed and gradually add ~~Eudragit L100-55~~ EUDRAGIT® L100 55 (poly(methacrylic acid-co-ethyl acrylate) 1:1) powder into the hydroalcohol mixture.
  - (d) Continue mixing until neutralization process is complete and no more effervescence is detected.
  - (e) Reduce the mixing speed and add nicotine oil into ~~Eudragit~~ EUDRAGIT® hydroalcohol solution.
  - (f) Cap the bottles and place it on the roller mixer for at least two hours for additional mixing and degassing

Please replace the table on page 13, entitled "Example 1. A monolayer nicotine containing film" with the following:

#### Example 1. A monolayer nicotine containing film.

| Ingredient  | Dry %      | Weight (mg) |
|---|------------|-------------|
| Nicotine Oil  | 3.33       | 2.01        |
| <del>Eudragit L100-55</del> <u>EUDRAGIT® L100 55 (poly(methacrylic acid-co-ethyl acrylate) 1:1)</u> | 52.25      | 31.38       |
| Triethyl Citrate  | 26.62      | 15.96       |
| Intensates Cool Peppermint  | 11.15      | 6.65        |
| Sucrolose   | 2.16       | 1.33        |
| Sodium Bicarbonate  | 4.49       | 2.66        |
| Disodium EDTA   | 0.02       | 0.01        |
| <b>Total</b>  | <b>100</b> | <b>60.0</b> |

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Please replace the table on page 13, entitled "Example 2. A monolayer nicotine containing film" with the following:

**Example 2. A monolayer nicotine containing film.**

| <b>Ingredient</b>  | <b>Dry %</b> | <b>Weight (mg)</b> |
|--|--------------|--------------------|
| Nicotine Oil   | 3.37         | 2                  |
| <del>Eudragit L100-55</del> <u>EUDRAGIT®</u><br><u>L100 55 (poly(methacrylic acid-</u><br><u>co-ethyl acrylate) 1:1)</u> | 50.08        | 29.7               |
| Triethyl Citrate   | 25.30        | 15.0               |
| Intensates Cool Peppermint   | 10.62        | 6.3                |
| Sucrose  | 2.02         | 1.2                |
| Sodium Bicarbonate   | 8.60         | 5.1                |
| <b>Total</b>   | <b>100</b>   | <b>59.3</b>        |

Please replace the paragraph beginning on page 14, line 1 with the following:

To produce a bilayer film, the enteric polymer (~~Eudragit L100-55~~ EUDRAGIT® L100 55  
(poly(methacrylic acid-co-ethyl acrylate) 1:1)), plasticizer (triethyl citrate), sweetener  
(Magasweet), taste masking agent (intensates), chelating agent (EDTA), neutralizing  
agent (sodium bicarbonate) and the active ingredient (nicotine oil) are dissolved in 60/40  
(ethanol/water) hydroalcohol with the pH greater than 4 but less than 7 as described  
below.

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Please replace the paragraph beginning on page 14, line 6 with the following:

- Enteric polymer layer:
  - (a) Weigh all excipients except ~~Eudragit L100-55~~ EUDRAGIT® L100 55 (poly(methacrylic acid-co-ethyl acrylate) 1:1) and nicotine oil into a hydroalcohol/water solution (ethanol/water 60/40).
  - (b) Using high speed mixer, dissolve all solids in the hydroalcohol/water solution.
  - (c) Increase the mixing speed and gradually add ~~Eudragit L100-55~~ EUDRAGIT® L100 55 (poly(methacrylic acid-co-ethyl acrylate) 1:1) powder into the hydroalcohol mixture.
  - (d) Continue mixing until neutralization process is complete and no more effervescence is detected.
  - (e) Reduce the mixing speed and add nicotine oil into ~~Eudragit~~ EUDRAGIT® hydroalcohol solution.
  - (f) Cap the bottles and place it on the roller mixer for at least two hours for additional mixing and degassing.

Please replace the table beginning on page 15, entitled "Example 3A - 3H depict bilayer films" with the following:

**Example 3A - 3H depict bilayer films:**

| Ingredient   | Ex. 3A  | Ex. 3B  | Ex. 3C  | Ex. 3D  |
|--|---------|---------|---------|---------|
|  | wt (mg) | wt (mg) | wt (mg) | wt (mg) |
| <b>Layer 1</b>   |         |         |         |         |
| Nicotine Oil   | 2.0     | 2.0     | 2.0     | 2.0     |
| <del>Eudragit L100-55</del><br><u>EUDRAGIT® L100 55 (poly(methacrylic acid-co-ethyl acrylate) 1:1)</u> | 35.5    | 34.1    | 32.7    | 19.7    |
| <del>Eudragit NE 30</del><br><u>EUDRAGIT® NE (Poly(ethyl acrylate-</u>                                 | 0       | 0       | 0       | 8.6     |

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|                                     |       |       |       |       |
|-------------------------------------|-------|-------|-------|-------|
| <u>co-methyl methacrylate) 2:1)</u> |       |       |       |       |
| Polysorbate 80                      | 0     | 0     | 0     | 11.1  |
| Triethyl Citrate                    | 10.9  | 17.1  | 22.7  | 0     |
| Intensates Cool Peppermint          | 6.8   | 6.6   | 6.3   | 4.3   |
| Megasweet L100                      | 4.1   | 3.9   | 3.8   | 2.6   |
| Sodium Bicarbonate                  | 0.7   | 1.3   | 2.5   | 1.7   |
|                                     |       |       |       |       |
| <b>Layer 2</b>                      |       |       |       |       |
| Lactose                             | 86.9  | 83.3  | 79.7  | 94.2  |
| Sorbitol                            | 7.6   | 7.2   | 6.9   | 8.2   |
| Disodium Phosphate                  | 9.4   | 9.1   | 8.7   | 10.2  |
| Megasweet 100                       | 3.8   | 3.6   | 3.5   | 4.1   |
| Silica                              | 2.8   | 2.7   | 2.6   | 3.1   |
| Intensates Cool Peppermint          | 9.4   | 9.1   | 8.7   | 10.2  |
| <b>Total Weight</b>                 | 180.0 | 180.0 | 180.0 | 180.0 |

| <b>Ingredient</b>  | <b>Ex. 3E</b> | <b>Ex. 3F</b> | <b>Ex. 3G</b> | <b>Ex. 3H</b> |
|--|---------------|---------------|---------------|---------------|
|  | <b>Dry %</b>  | <b>Dry %</b>  | <b>Dry %</b>  | <b>Dry %</b>  |
| <b>Layer 1</b>   |               |               |               |               |
| Nicotine Oil   | 13.8          | 13.5          | 13.5          | 13.8          |
| <del>Eudragit L100-55</del><br><u>EUDRAGIT® L100 55 (poly(methacrylic acid-co-ethyl acrylate) 1:1)</u> | 42.2          | 40.4          | 40.4          | 42.2          |
| Sodium EDTA  | 0.2           | 0.2           | 0.2           | 0.2           |
| Sodium Bicarbonate   | 6.5           | 5.8           | 5.8           | 6.5           |
| Triethyl Citrate   | 24.3          | 26.9          | 26.9          | 24.3          |
| Intensates Cool  | 8.1           | 9.0           | 9.0           | 8.1           |

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|                    |      |      |      |      |
|--------------------|------|------|------|------|
| Peppermint         |      |      |      |      |
| Megasweet L100     | 4.9  | 4.5  | 4.5  | 4.9  |
| <b>Total</b>       | 100  | 100  | 100  | 100  |
|                    |      |      |      |      |
| <b>Layer 2</b>     |      |      |      |      |
| Lactose            | 68.6 | 68.6 | 52.8 | 52.8 |
| Polysorbate 80     | 0.7  | 0.7  | 0.7  | 0.7  |
| Disodium Phosphate | 7.1  | 7.1  | 7.3  | 7.3  |
| Megasweet 100      | 2.9  | 2.9  | 2.9  | 2.9  |
| Methanol           | 7.1  | 7.1  | 7.3  | 7.3  |
| Silica             | 2.2  | 2.2  | 2.6  | 2.6  |
| Sorbitol           | 0    | 0    | 26.4 | 26.4 |
| Glycerin           | 11.4 | 11.4 | 0    | 0    |
| <b>Total</b>       | 100  | 100  | 100  | 100  |